K003035

JUN - 6 2001

APPENDIX F

510(k) SUMMARY

Clarren Helmet

Children's Hospital & Regional Medical Center

This 510(k) summary of safety and effectiveness for the Clarren Helmet is submitted in accordance with the requirements of SMDA and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	Children's Hospital & Regional Medical Center
Address:	4800 Sand Point Way, N.E. Box 5371/CH-01 Seattle, WA 98105-0371
Contact Person:	Jeffrey M. Sconyers, Esq. Vice-President & General Counsel
Telephone:	(206) 526-2286 (telephone) (206) 527-3830 (fax)
Preparation Date:	August 2000
Device Trade Name:	Clarren Helmet
Common Name:	Cranial Orthosis
Classification Name:	Cranial Orthosis (see 21 C.F.R. § 882.5970) Product Code: MVA
Device Description:	The Clarren Helmet is a cranial orthosis that applies passive pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly. It consists of a polypropylene sheet, three-eighths of an inch thick, that is vacuum formed over a plaster model of a baby's head to produce a helmet. A liner for the helmet is made of Plastizote, one-fourth of an inch in thickness. Small holes are bored in the helmet for ventilation, and large holes for the child's ears. A velcro chin strap is attached to help keep the helmet in place on the baby's head.
Intended Use:	The Clarren Helmet is a cranial orthosis that applies passive pressure to prominent regions of an infant's cranium in order

to improve cranial symmetry and/or shape in infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic- shaped heads.

Performance Data:

Clarren, Sterling, M.D., "Plagiocephaly and torticollis: Etiology, natural history, and helmet treatment," *Journal of Pediatrics*, 98:1 (92-95) (Jan. 1981); Clarren, et al., "Helmet treatment for plagiocephaly and congenital muscular torticollis," *Journal of Pediatrics*, 94:1 (43-46) (Jan. 1979).

CONCLUSIONS:

Based on the foregoing and other information in this application, Children's Hospital & Regional Medical Center believes that the performance data provide reasonable assurance of the safety and effectiveness of the Clarren Helmet for its proposed indications for use. Further, the Clarren Helmet is substantially equivalent to its claimed predicate under conditions of intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Children's Hospital & Regional Medical Center
David J. Bloch, Esq.
Regulatory Counsel
c/o Reed Smith Shaw & McClay
1301 K Street, N.W., Suite 1100-East Tower
Washington, D.C. 20005-3317

Re: K003035
Trade Name: Clarren Helmet
Regulation Number: 882.5970
Regulatory Class: II
Product Code: MVA
Dated: April 16, 2001
Received: April 18, 2001

Dear Mr. Bloch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003035

Device Name:_____

Indications For Use:

Indications for use:

The Clarren Helmet is a cranial orthosis that applies passive pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic- shaped heads.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003035

(Optional Format 3-10-98)